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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/640,853
Filing Date: August 13, 2003
Appellant(s): SPARER ET AL.

Christopher D. Gram
Reg. No. 43,643
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 03/28/2008 appealing from the Office action mailed 11/05/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

10/640,714

10/640,702

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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6,110,483	Whitbourne et al.	8-2000
US 2002/0082679 A1	Sirhan et al.	6-2002
US 2004/0012118 A1	Perez et al.	1-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al. (US 2002/0082679 A1).

Sirhan teaches a luminal prosthesis that can be in the form of a stent, the stent can further contain a rate-controlling element formed from polymers including cellulose acetate butyrate (CAB), polyethylene vinyl acetate (PEVA), polyurethane, polycarbonates, polymethylmethacrylate and the like and mixtures and combinations thereof, the rate controlling element provides for a controlled release of at least one active ingredient that can be contained within the element. See abstract, [0046]-[0050],[0053] and claims 1,18,74-76,80-82,112-118 and 126. The active ingredient included numerous therapeutics including dexamethasone, azatioprine and prednisone,

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all of the above active ingredients are also disclosed as active ingredients within applicants own specification. See claim 18 and [0030]. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as $10,5$ or $3 \text{ J}^{1/2}\text{cm}^{3/2}$, Sirhan teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that the miscible polymer blend initially provides a barrier to permeation, this limitation is met, since Sirhan teaches the use of the same polymers in a mixture with the active agent contained within that the polymer it will provide the same barrier to permeation since the polymers are the same then their release properties will inherently be the same. Regarding the limitations that at least one polymer has a higher diffusivity and one lower than the target diffusivity, this limitation is met since it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. Regarding the limitation on swellability for the polymer blend which is no more than 10% by volume, this limitation is

met, because Sirhan teaches the use of polymeric films within the scope of the applicants claims therefore it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver an active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75-78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Sirhan who teaches a method to make the same polymer blend as claimed by applicant, the blend incorporated a bioactive agent, therefore the polymer blend would control the delivery of the bioactive agent in the same way as applicants claims since the same composition will inherently have the same properties.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252).

Hossainy teaches a coating for stents and a method for forming the coated stent having a film forming biocompatible polymer coating in which different polymers may be used for different layers (polyurethanes, polyamides, polyesters, polymethacrylates polyolefins, ethylene methyl methacrylate copolymers various hydrophilic celluloses and many other hydrophobic and hydrophilic polymers were specifically listed) in which the top coat (either a film or matrix) can be used to deliver therapeutic and pharmaceutical agents (including fluorouracil which is disclosed as an active ingredient within applicants own specification). See col 1 lin 6-9, col 2 lin 9-19, col 4 lin 15-col 5 lin 38, col 7 lin 5-

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11, lin 56-col 8 lin 35, col 9 lin 20-25, fig. 6 and 7. See col 7 lin 18-55. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10.5 or $3 \text{ J}^{1/2} \text{ cm}^{3/2}$, Hossainy teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. Regarding the limitation that the miscible polymer blend initially provides a barrier to permeation, this limitation is met, since Hossainy detailed the use of a top coating to delay release of the pharmaceutical agent. Regarding the limitations that at least one polymer has a higher diffusivity and one lower then the target diffusivity is met since the target diffusivity is determined by the preselected time for delivery and the preselected critical dimension of the polymer which is taught by Hossainy; it is inherent that the diffusivity for the polymer films (also their TG diffusivities) and the active agent would be the same as the applicants since the polymeric films and the active agents are the same. See col 7 lin 18-55, fig. 6 and 7. Regarding the limitation on swellability for the polymer blend which is no more than 10% by volume, this limitation is met, because Hossainy teaches the use of polymeric films

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within the scope of the applicants claims therefore it is inherent that since the polymer films are the same they will have the same swellability by volume. Regarding claims 71-74 it is inherent that a stent, being an implantable device, would deliver an active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75-78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Hossainy who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active agent in the same way as applicants newly entered claims.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483).

Whitbourne teaches a coating for biomedical devices (including stents) and the method to make the coatings in which the coating is a blend of a stabilizing polymer and an active agent comprised of a hydrophilic polymer (the blends can include the following: polyurethanes, acrylic polymers, methacrylic polymers, vinyl acetal polymers, polyethers, PVP, epoxy polymers, several hydrophilic celluloses and numerous other stabilizing and hydrophilic polymers/copolymers) the coating also comprises a bio-active agent contained within (including thymol which is disclosed as an active ingredient within applicants own specification). See col 1 lin 5-12, lin 65-col 2 lin 24, lin 31-38, lin 43-47, col 3 lin 21-59, col 4 lin 13-36, col 5 lin 28, lin 41-46, col 7 lin 15-17, lin 55-56, col

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9 lin 29-32, 50-54 and claim 17. Regarding the selection of the first and second polymer and active ingredient based upon their solubility parameters being no greater than a certain range such as 10,5 or $3 \text{ J}^{1/2} \text{ cm}^{3/2}$, Sirhan teaches the mixtures of the same polymers and active ingredients as applicants claimed invention, therefore it is inherent that the same polymers and actives will have the same solubility parameters. It appears as though applicants are claiming a new and/or undiscovered property of an old composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Regarding the limitation that "the miscible polymer blend initially provides a barrier to permeation" this limitation is met, since Whitbourne discusses a time-release effect of the active ingredient attributable to the interaction of the bioactive agents with the stabilizing polymer. See col 3 lin 56-59. Regarding the limitation that the swellability for the polymer blend is no more than 10% by volume, this limitation is met, because Whitbourne discusses the swellability of the hydrophilic polymer in the composition, while the patent discussed the swellability in terms of weight not volume it is inherent that by blending with a non-swelling polymer the blend could have swelling of no greater than 10% of its own volume, also since the polymers are the same so will be their physical properties such as swelling. See col 5 lin 1-12. Regarding the limitation that at least one polymer has a higher diffusivity and one lower than the target diffusivity, this is

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considered inherent by the examiner (see above). Regarding claims 71-74 it is inherent that a stent being an implantable device would deliver any active agent to a bodily fluid, organ or tissue of a subject when a polymer film containing an active agent coats that stent. Regarding the limitations in claims 75-78 on a method of tuning the delivery of an active agent and a miscible polymer blend by selecting at least two miscible polymers to form a miscible polymer blend that controls the delivery of the active agent, this is met by Hossainy who teaches a method to make the same polymer blend as claimed by applicant and detailed the use of a top coating to delay release of the pharmaceutical agent, therefore the polymer blend controls the delivery of the active agent in the same way as applicants newly entered claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al. (US 2002/0082679 A1).

Sirhan is disclosed above. The Sirhan patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Sirhan is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Sirhan encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081] within Perez. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon what is

already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252).

Hossainy is disclosed above. The Hossainy patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Hossainy is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Hossainy encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081]. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon

what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483).

Whitbourne is disclosed above. The Whitbourne patent is silent on the solubility parameter value of the biocompatible polymeric films and the active agent. Even though Whitbourne is silent on the solubility parameters of the polymers and active agents and using the parameters to select the polymers and actives that would be miscible with each other, it is still obvious that since Whitbourne encompasses many of the same polymers and active agents as applicants currently claimed invention it meets these limitations since obviously the same compounds will have the same solubility parameters. Besides this argument it is further evidenced by the disclosure within Perez (US 2004/0012118 A1, submitted in applicants IDS) that it was already understood in the art to use solubility parameters to predict if polymers would be miscible, See [0030] and [0081]. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters and it would also be obvious to the skilled artisan that any active ingredients incorporated within the miscible polymer blends should also be relatively close in solubility to at one of the polymers in order to form a uniform miscible blend. [W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. The normal desire of scientists or artisans to improve upon

what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

(10) Response to Argument

35 U.S.C. 102(b) rejections over Hossainy et al. (US 6,153,252), Whitbourne et al. (US 6,110,483) and Sirhan et al. (US 2002/0082679 A1).

Appellants assert that the references above fail to specifically point out and distinctly set forth each and every feature recited within the claims. Specifically appellants assert that none of the references above expressly or inherently teach a method that includes forming a miscible polymer blend by the conscious, deliberate and discretionary step of selecting a second polymer based on its miscibility with a first polymer and having the specified difference in solubility parameter compared to a hydrophobic cellulose derivative. Appellants assert that the references above cannot read on their claimed invention because their claims are drawn to a novel method and are not drawn to a polymer blend, thus even though the references above all contain possible but unidentifiable polymer blends they do not recite the claimed method steps. Applicants also assert that each independent claim further describes selecting a second polymer so that the components of the active agent delivery system, i.e., polymers and/or active agents possess one or more additional properties and/or relationships including difference in solubility parameter between the active agent and at least one polymer, differences in solubility parameter between polymer, diffusivity, molar average

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solubility parameter, swellability, glass transition temperature and/or difference in swellabilities.

The examiner disagrees with appellant's remarks above. Firstly appellants attempt of limiting the independent claims so the second polymer is **selected** to be miscible with the first polymer or so that it has some type of relationship with the active ingredient is a **mental process or abstract idea** and is not a patentable difference in view of the prior art. The reasons to select the polymer blend in the references above may indeed be different then choosing them based on their miscibility properties or its properties compared to an active, however a **mental process of selecting** polymers is not a **patentable distinction** that can preclude appellants claimed invention from the prior art. Since a mental process or abstract idea of selecting a polymer is not patentable material and cannot be considered as a limitation, the examiner conducted his search of the prior art on a method of making a device containing a blend of two polymers and an active agent that are within the scope of appellants claims. The examiner concluded that a method of forming an active agent delivery system comprising a polymer blend does have utility, however the examiner cannot consider limitations that do not lead to a patentable distinction, **an abstract idea or mental process limitation within a claim set is not a patentable distinction** that the examiner can consider when applying prior art. Thus since as previously stated all of the above references teach a process to make a polymer blend containing an active ingredient appellants' limitations within the claims are met. The subject matter courts have found to be outside of or exceptions to, the four statutory categories of invention is

limited to abstract ideas, laws of nature and natural phenomena. These three exclusions recognize that subject matter that is not a practical application or use of an idea, a law of nature or a natural phenomenon is not patentable. See MPEP § 2106.

Appellants also assert that the above references merely recite long laundry lists of general classes of polymers, some of the members of which could conceivably be miscible with other members of the recited general classes.

Regarding Sirhan the polymers claimed by appellants are also claimed within Siran, thus the polymers are hardly laundry lists of ingredients rather they are essential ingredients to the claimed invention. Whitbourne claims polyvinyl acetals and acetates, acrylic polymers, methacrylic polymers meeting appellants claimed second polymer and also claims an active agent that included several cellulose derivatives and polyurethanes as detailed within the disclosure of the specification. Hossainey claims several cellulose derivatives within the claims and the description of the specification list polyamides, polyesters, polymethacrylates polyolefins, and ethylene methyl methacrylate copolymers as useful ingredients in the polymer film. Thus from the claimed invention of Whitbourne and Hossainey and the descriptions of other polymers that are useful within their respective specifications one of ordinary skill in the art would have readily envisaged from the teachings of Whitbourne and Hossainey appellants claimed drug delivering polymer blend and the method to produce it. Also in regards to Whitbourne and Hossainey, the prior art's mere disclosure of more than one alternative

does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.

Appellants further assert that the references above cannot inherently teach combinations of polymers that encompass the claimed first and second polymer blend recited in appellant's claims for at least three reasons. Appellant's first reason is that even if the references teach similar coatings to their claimed invention it is irrelevant because the claims are not drawn to the coatings themselves but to methods in which the coatings are formed. Appellants further assert in relation to their first point that the examiner has erred in stating that selecting two polymers based on their solubility parameters is not an actual limitation because the claims clearly state that the second polymer is chosen in part on its solubility properties and the second polymer is selected to be miscible with the first polymer. Secondly appellant's state inherency is impermissible because the examiner has not pointed to methods described in the references above on selecting a second polymer to be miscible with and possess the recited difference in solubility compared to the cellulose derivative. Thirdly appellants assert that the references describe a broad genus of possible combinations of polymers wherein the blends of polymers in appellant's method claims are a subgenus, thus the genus described in the references cannot anticipate appellant's claimed subgenus.

As stated above the examiner did not search for the mental process or abstract idea of selecting a polymer based on selecting it to be miscible with a hydrophobic cellulose, rather the examiner searched for the portion of the claim that was statutory subject matter; a method of forming an active agent delivery system containing an

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active ingredient and a miscible polymer blend. Thus since as previously stated all of the above references teach a process to make a polymer blend containing an active ingredient appellant's limitations within the claims are met. As detailed above a mental process to select polymers based on their miscibility properties is not a true limitation that can be considered for a process to form a device. Regarding appellant's assertion that the references describe a broad genus of possible polymer combinations, while their claims are a subgenus, the relevance of this assertion is unclear, clearly as detailed in previous office actions and in the rejections and remarks above all the references teach the same polymer combination as claimed by appellants.

35 U.S.C. 103(a) rejections over Hossainy et al. (US 6,153,252), Whitbourne et al. (US 6,110,483) and Sirhan et al. (US 2002/0082679 A1).

Appellants assert that the references above fail to teach or suggest all of the recited features within the claims, specifically as in the arguments summarized above appellants assert that none of the references teach or suggest selecting polymers based upon their miscibility or difference in solubility parameters. Applicants also assert that none of the references above disclose selecting the active ingredient a 1st and 2nd polymer to balance one or more plurality of properties, and/or relationships between, components in order to achieve the desired character of the delivery system as a whole.

For the same reasons as outlined above the examiner disagrees, the remarks by the examiner above for the process of selecting a polymer based upon its miscibility with another polymer or its properties/relationships with the other components such as the active is incorporated herein. Essentially the abstract idea or mental process of

selecting a polymer based upon its miscibility or its properties compared to the other ingredients present in the delivery system is not a limitation that the examiner considered when applying the prior art.

Appellants assert that there is no motivation within any of the references above either implicitly or explicitly make a tunable agent delivery system that includes a miscible polymer blend prepared by selecting one of the specified first polymers to be miscible with a second polymer so that the delivery system possesses the one or more particularly identified properties and/or relationships. Appellants also reiterate two points above on how the references do not inherently disclose their claimed invention because a) their claims are drawn to a method of producing an active agent delivery system, b) the disclosures of the references above are insufficient because they all disclose a genus of polymer combinations while their claims are drawn to a species of polymer combinations.

Firstly as described above the examiner did not treat the mental process of selecting a polymer based on its miscibility with the other polymer as being a patentable distinction between appellants claims and the prior art. Thus since the references above all disclose a process to make a polymer blend containing an active agent appellants claims are prima facie obvious in view of the cited art above. Regarding appellant's assertion that the references describe a broad genus of possible polymer combinations, while their claims are a subgenus, the relevance of this assertion is unclear, clearly as

detailed in previous office actions and in the rejections and remarks above all the references disclose the same polymer combination as claimed by appellants.

Appellants assert that Perez does not cure the deficiencies of Hossainy, Siran or Pirez because none of the references disclose or suggest the general nature of tuning an active agent using a miscible polymer blend.

Firstly Perez was only used as evidence to show that the mental process of selecting polymers based upon their solubility properties was well known in the art at the time of appellant's invention. However this point as well as appellants arguments above are actually moot, since as described above the examiner did not treat the mental process of selecting a polymer based on its miscibility with the other polymer as being a patentable distinction between appellants claims and the prior art.

Appellants assert that there is no reasonable expectation of successfully forming a tunable active agent delivery system by selecting polyvinyl polymers to be miscible with the hydrophobic cellulose derivative in the references cited above.

Once again as described above the examiner did not treat the mental process of selecting a polymer based on its miscibility with the other polymer as being a patentable distinction between appellants claims and the prior art. Thus the argument above is moot since the mental process was not treated as a limitation within the claims.

(11) Related Proceeding(s) Appendix

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No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/James W Rogers, Ph.D./

Examiner, Art Unit 1618

Conferees:

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